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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/365,241	07/30/99	BRODIN T	003300-581

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EXAMINER	
WESSENDORF, T	
ART UNIT	**PAPER NUMBER**
1627	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/365,241	Applicant(s) Brodin et al
	Examiner T. Wessendorf	Group Art Unit 1627

☒ Responsive to communication(s) filed on *9/14/00*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-60* is/are pending in the applicat

Of the above, claim(s) *58-60* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-57* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *6*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The abstract is objected to because of the inclusion of the phraseology often used in patent claims. For example, "comprises".

The specification has not been checked to the extent necessary to determine the presence of **all** possible minor errors (grammatical, typographical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Applicants' election with traverse of Group I in Paper No. 12 is acknowledged. The traversal is on the ground(s) that there is no undue burden on the Examiner to examine all of the claims in a single application. This is not found persuasive because, as applicants' recognize the restriction is appropriate since the inventions are distinct and independent. Furthermore, examination of all the claims would indeed impose a burden since the binding structures would be of infinite scope as included in the broad scope of the binding structures. It is not seen how an overlap in the examination exists between the two inventions when the binding structures, particularly the specific ones, may not necessarily be produced by the instant screening process. Since there is no overlap in the examination of the distinct and different inventions and the searches go beyond the Patent search

(e.g., literatures), the search of these distinct inventions does impose a burden. With respect to the species restriction, since applicants present the same argument that the search of each species would not be burdensome, the rebuttal above is similarly applied. Each of the claimed species e.g., those defined as the binding structures comprise structurally, functionally different biochemical compounds such as antibodies, hormones, enzymes, receptors, ligands, peptides etc. and non-biochemical compounds as the different recited organochemical groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 58-60 are withdrawn from further consideration pursuant to 37 CAR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12. Claims 1-57 are pending in the application and would be examined to the extent of the elected species.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 1 is indefinite in the recitation of acquiring a binding structure(s) which appears that it is the compound structure(e.g., tertiary or secondary) that is obtained rather than conventionally a compound e.g., antibodies or antigen or ligand or receptor. Also, the phrase " by means of a first library of binding structures" is unclear, within the claimed context, as to the means by which a binding structures is obtained. The recited "other identifying information" is indefinite as to which the term "other" refers to and unclear as to what is covered by said other information and when use with the phrase "and/or" renders it more indefinite. The terms "first" and "second" libraries are indefinite as these are relative terms, the basis or standard by which a library is considered a first or a second library is not positively defined in the specification or claims. The whole process steps is in fact

confusing. How can a first library be reacted with a target structure in vivo and in situ, how is such reaction determine and how is the target structure displayed in vivo and in situ? How can the target be displayed when it is the binding structure that is linked to the gene? The term "authentic", within the claimed context, is indefinite. What would be considered an authentic phenotype, within the claimed context? The claims use terminologies which are so different from that which is generally accepted in the art. Applicants are required to provide a clarification of these languages or correlation with art-accepted terminologies.

The term "characterized" to describe a process is confusing since it is unclear as to the process steps involve and the term is more applicable for a compound that is characterized by its properties. E.g., claims 2-5.

Claim 4 is indefinite in the scope of "etc." Also, the terms single-entity, homogenous(misspelled), uniform and/or other binding structures are indefinite as the metes and bounds of said structures are unclear e.g., whether a binding structure (compound) possesses all of the above characterizations or are different and separate entities. The terms "third" and "fourth library" lack antecedent basis of support from the base claim and

broadens the base claim which does not recite for said third or fourth library.

Claim 6 is indefinite as it is not clear as to what are included in the previously uncharacterized, unpurified and unknown molecules.

Claim 7 is indefinite and lacks antecedent basis of support from the base claim in the recitation that the target structure is expressed. It is not clear how the target structure is expressed when the gene includes only the binding structure.

Claim 8 does not further limit the base claim since the limitation recited in claim 8 is already present in the base claim.

Claims 11 and 14 lack antecedent basis of support from the base claim which does not recite for a set of displayed target structures. Furthermore, it is not clear, within the claimed context, the differentiation between a desired and undesired target structures.

Claims 12 and 13 do not further limit the base claim since the step of recovery of the bound and unbound structures is already recited in the base claim.

Claims 15 and 16 are duplicates of claims 12 and 13 as these claims contain the same limitations.

Claim 22 is indefinite as to the metes and bounds of a portion or set of antigens. Also, the claim to said portion and set is unclear as the portion is already included in the whole.

Claim 23 is indefinite in the recitation that the target is based on protein. How is it based on a protein, when the target is a protein.

Claims 24-27 are confusing as to how the base claim method of obtaining e.g., an antibody is further limited. These method is directed to a different method of obtaining e.g., a tissue section.

Claims 30 and 32, for example, are unclear, within the claimed context, as to the passive or active secretions of e.g., body fluids.

Claim 39 is unclear as to the basis or standard of preselection of a library.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> a person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-50 and 54 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any one of Tse et al (WO 94/26787) or Cai et al (PNAS) or Williams et al(Immunotechnology)or under 102(e) over either Rouslahti et al (5,622,699) or O'Mahony (6,117,632).

Tse discloses a method for generating antibody directed against a tumor antigens comprising a method of incubating a combinatorial library of antibodies expressed on the surface of filamentous phage particles with a target populations including whole tissue sections such as frozen tissue sections, in which the target cell population is identifiable. See e.g., page 5, line 22 up to page 6, line 2, under conditions sufficient to bind a portion of the phage particles to the target cells. The target

cells and bound phage particles are then separated from the unbound phage particles and the bound phage particles are recovered. These phage particles are then amplified to create an enriched library. Monoclonal antibodies specific to the target cells are then isolated from the enriched library for subsequent use. See page 2, lines 13-38 and the Examples pages 8-10. The phage library of antibody is contacted against target antigens on the surface of a phenotypically defined population of tumor cells and used to separate phage antibodies reactive to the antigens from the background. The cell membrane of the target cells can be considered a solid phase support for a set of cell type specific antigens, and the intact target cells can be used as a convenient physical device to separate phage antibodies bound on the surface of the target cells from the unbound phage antibodies, isolating the bound antigen-antibody complex from the unbound ones, recovering a single phage particle containing antibody specifically bound to an antigen and amplifying the bound complex. Therefore, the broadly claimed process steps is anticipated or rendered obvious by the specific process steps of Tse which employs specific binding and target structures.

Cai basically discloses the same method as Tse above. See specifically page 6280, Materials and Methods heading up to page 6284, col. 1.

See the entire abstract of the Williams reference, pp.295-296.

Rouslahti basically discloses the same method of identifying antibodies from a phage display antibody using in vivo method. See e.g., the Examples, col. 15, line 20 up to col. 30, line 28.

See O'Mahony at e.g., col. 17, Example 1 up to col. 30.

No claim is allowed.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1627.

Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993)(see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO

DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat Ph.D., can be reached on (703) 308-0570. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

T. Wessendorf
Patent Examiner
Art Unit 1627
11/3/00